## **CLAIMS**

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- 1. A pharmaceutical aerosol formulation to be administered by pressurized metered dose inhalers which comprises an active ingredient selected from salmeterol or a stereoisomer, physiologically acceptable salt and solvate thereof, in solution in a propellant system, said propellant system consisting of a liquefied HFA propellant, a co-solvent and 0 to 5% w/w water, characterised in that the amount of the cosolvent is no more than 35% w/w on the total weight of the formulation.
- 2. A pharmaceutical formulation according to claim 1, wherein the co-solvent is selected from the group of lower alkyl (C1-C4) alcohols, polyols, polyalkylene glycols, (poly)alkoxy derivatives and their combinations.
  - 3. A pharmaceutical formulation according to claim 2 wherein the cosolvent is ethanol.
- 4. A pharmaceutical formulation according to claim 3 wherein the amount of water is from 0.5% to 5% w/w and ethanol is no more than 25% w/w.
  - 5. A pharmaceutical formulation according to claims 1-4 wherein the amount of water is up to 3% w/w.
- 6. A pharmaceutical formulation according to claims 1-5 wherein the fraction of particles equal to or less than 1.1 μm delivered on actuation of the inhaler, the superfine fraction, is higher than or equal to 30% as defined by the content of the stages S6-AF of an Andersen Cascade Impactor, relative to the content of the stages S6-AF, according to the method referred to in the description on page 16 lines 16 to 24.
- 25 7. A pharmaceutical formulation according to claims 1-6 wherein the superfine fraction is higher than 40%.
  - 8. A pharmaceutical formulation according to claims 1-7 wherein the active ingredient is salmeterol xinafoate.

23

- 9. A pharmaceutical formulation according to claim 8 wherein the active ingredient is in a concentration of between 0.005 and 0.15% w/v.
- 10. A pharmaceutical formulation according to any preceding claim wherein the pH is comprised between 2.5 and 5.5.
- 5 11. A pharmaceutical formulation according to claim 10 wherein the pH is adjusted by adding a mineral acid.
  - 12. A pharmaceutical formulation according to any preceding claim, wherein the propellant includes one or more hydrofluoroalkanes [HFAs] selected from the group comprising HFA 134a and HFA 227.
- 10 13. A pharmaceutical formulation according to claims 1-12 comprising 0.04% w/v salmeterol, 15% w/w ethanol and 2% w/w water.
  - 14. A pharmaceutical formulation according to any preceding claim filled in a canister having part or all of its internal metallic surfaces made of standard aluminium, stainless steel, anodised aluminium or lined with an inert organic coating.
  - 15. A pharmaceutical formulation according to any preceding claim comprising a further active ingredient selected from the class of steroids such as beclomethasone dipropionate, fluticasone propionate, ciclesonide, budesonide and its 22R-epimer or anticholinergic atropine-like derivatives such as ipratropium bromide, oxitropium bromide, tiotropium bromide.
  - 16. A method of preparing the pharmaceutical formulations of claims 1-15, the method comprising:
  - (a) preparing of a solution of one or more active ingredients in one or more co-solvents;
- 25 (b) optionally adding a proper amount of water and adjusting the pH of the solution;
  - (c) filling of the device with said solution;
  - (d) crimping with valves and gassing.

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- (e) adding a propellant containing a hydrofluoroalkane (HFA).
- 17. A method according to claim 16 wherein the device in provided with a valve actuator whose orifice diameter is 0.22 mm.
- 18. A pharmaceutical formulation according to any one of claims 1 to 17
  5 for the treatment of respiratory diseases.
  - 19. A pharmaceutical formulation according to claim 18 in which the respiratory disease is asthma or Chronic obstructive pulmonary disease (COPD).
- 20. A pharmaceutical formulation according to claim 19 in which the respiratory disease is due to obstruction of the peripheral airways as a result of inflammation or mucus hypersecretion.
  - 21. A pharmaceutical formulation according to claim 18 wherein the respiratory disease is pulmonary edema or surfactant-deficiency related disorder such as acute lung injury (ALI) or acute respiratory distress syndrome (ARDS).

15